Thidiazuron

Interim Registration Review Decision
Case Number 4092

September 2016

Approved by: _____
Yu-Ting Guilaran
Director
Pesticide Re-evaluation Division

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I. INTRODUCTION

This document is the Environmental Protection Agency's (EPA or the Agency) *Interim Registration Review Decision* for thidiazuron (case 4092, PC code 120301), and is being issued pursuant to 40 CFR sections 155.56 and 155.58. A registration review decision is the Agency's determination whether a pesticide meets, or does not meet, the standard for registration in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The Agency may issue, when it determines it to be appropriate, an interim registration review decision before completing a registration review. Among other things, the interim registration review decision may: 1) require new risk mitigation measures; 2) impose interim risk mitigation measures; 3) identify data or information required to complete the review; and 4) include schedules for submitting the required data, conducting the new risk assessment, and completing the registration review. For further information on thidiazuron, additional documents can be found in EPA's public docket (EPA-HQ-OPP-2015-0381) at www.regulations.gov.

FIFRA, as amended by the Food Quality Protection Act (FQPA) of 1996, mandated the continuous review of existing pesticides. All pesticides distributed or sold in the United States generally must be registered by the EPA based on scientific data showing that they will not cause unreasonable risks to human health or to the environment when used as directed on product labeling. In 2006, the Agency implemented the registration review program pursuant to FIFRA section 3(g) and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration. The registration review program is intended to make sure that, as the ability to assess and reduce risk evolves, and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the Agency periodically re-evaluates pesticides to make sure that as these changes occur, products in the marketplace can continue to be used safely. Information on this program is provided at https://www.epa.gov/pesticide-reevaluation/registration-review-process.

EPA is issuing an interim registration review decision for thidiazuron so that it can: (1) move forward with aspects of the registration review that are complete, and (2) implement interim risk mitigation. The Agency is currently working with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service (together, the Services) to develop methodologies for conducting national threatened and endangered (listed) species assessments for pesticides. Therefore, although EPA has not yet fully evaluated risks to listed species, the Agency will complete its listed species assessment, and any necessary consultation with the Services for thidiazuron, prior to completing the thidiazuron registration review. Likewise, the Agency will complete endocrine screening for thidiazuron, pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA) section 408(p), before completing this registration review. Lastly, EPA will determine whether additional pollinator exposure and effects data are necessary in order to make a final registration review decision for thidiazuron and issue a data call-in (DCI) to obtain any such data prior to completing the thidiazuron registration review.

The first pesticide product containing thidiazuron was registered in 1982. Thidiazuron is a phenylurea plant growth regulator registered for use as a pre-harvest defoliant in cotton.

Thidiazuron acts to reduce the foliage and immature fruiting structures which contribute to the staining of harvested cotton and also acts to facilitate cotton harvesting. The last comprehensive human health and ecological risk assessments for thidiazuron were completed in 2005 in support of the Reregistration Eligibility Decision (RED). Pursuant to 40 CFR section 155.50, EPA formally initiated registration review for thidiazuron (case 4092) in June 2015. EPA streamlined its risk assessment process for thidiazuron by publishing its work plan at the same time as its risk assessment. Registration review for thidiazuron was streamlined for the following reasons:

i) thidiazuron is only used on one crop in a geographically limited area of the United States,
ii) the use pattern for thidiazuron has not changed since implementation of the RED label changes,
iii) the human health, ecotoxicology, and environmental fate databases for thidiazuron are mostly complete,
iv) the existing honey bee data did not indicate risks to pollinators, and
v) only minor updates to the risk assessments conducted in support of the RED were required to meet current risk assessment standards.

A. Summary of Thidiazuron Registration Review

The following highlights are significant events that have occurred during the registration review of thidiazuron, and can be found in the public docket (EPA-HQ-OPP-2015-0381), available at www.regulations.gov:

- June 22, 2015 – Publication of the thidiazuron *Preliminary Work Plan (PWP)* for a 60-day public comment period. The PWP was accompanied by the *Joint Problem Formulation and Draft Risk Assessment of the Environmental Fate and Ecological Risk of Thidiazuron*, and the *Human Health Combined Scoping Document and Draft Risk Assessment for Registration Review*. One public comment was received from Bayer during the 60-day comment period for the thidiazuron PWP. Bayer's comment covered the anticipated pollinator data requirements, chronic drinking water risks to birds, risks to terrestrial plants, and provided technical corrections where there were errors in EPA's documents. The Agency's response to Bayer's comment is set forth in the *Thidiazuron – EFED Responses to Comments from Bayer CropScience on the Draft Environmental Fate and Ecological Risk Assessment in Support of Registration Review. Docket ID: EPA–HQ–OPP–2015-0381-0008*, which can be found in the public docket (EPA-HQ-OPP-2015-0381), at www.regulations.gov. The public comment received did not result in changes to the Agency's work plan or risk assessments for thidiazuron.

- March 31, 2016 –The Agency issued the *Thidiazuron Proposed Interim Registration Review Decision (PID)* for a 60-day comment period. The PID was accompanied by the following support documents:
  - *Draft Risk Management Plan and Rationale for Thidiazuron*
  - *Environmental Fate and Effects Division's Phase 2 Risk Assessment for the Reregistration Eligibility Decision of Thidiazuron for Use on Cotton*
  - *Reregistration Eligibility Decision for Thidiazuron List D Case 4092*
  - *Thidiazuron-Quick Sit-down with EFED*
  - *Thidiazuron Risk Mitigation Teleconference: Meeting Notes*

- *Thidiazuron Usage and Benefits Information (PC# 120301)*
- *Thidiazuron – EFED Responses to Comments from Bayer CropScience on the Draft Environmental Fate and Ecological Risk Assessment in Support of Registration*

During the 60-day comment period on the *Thidiazuron Proposed Interim Registration Review Decision*, which opened on April 21, 2016 and closed on June 20, 2016, the Agency received comments from the Center for Biological Diversity (CBD) and the National Cotton Council (NCC), which are summarized below. The public comments in their entirety are located in the docket, EPA-HQ-OPP-2015-0381.

- September 2016 – The Agency is now publishing the *Thidiazuron Interim Registration Review Decision*. As noted, the Agency received public comments from CBD and the NCC in response to the proposed interim registration review decision. Discussion of the comments and the Agency's responses follow.

B. Public Comments and Agency Response

Comments submitted by the National Cotton Council (NCC) in EPA-HQ-OPP-2015-0381-0021.

1. Comment: *The NCC commented on the importance of thidiazuron as a cotton harvest aid, and stated that it believes pollinators are not present around cotton at the harvest preparation stage. The comment from the NCC also stated that the NCC does, and will, continue to seek research and educational means to minimize drift concerns. With regard to the Agency's approach to addressing ESA concerns, the NCC is concerned that the Agency's proposed approach lacks scientific credibility in favor of overly protective measures that jeopardize agriculture.*

   Response: The Agency thanks the NCC for their comments. The Agency's understanding of exposure to pollinators in cotton is informed by the USDA and their classification of cotton as a pollinator attractive crop. Although current data indicate that thidiazuron is not very toxic to bees, exposure to pollinators cannot be precluded because cotton flowering is intermittent and some flower buds may still be open during thidiazuron application. In addition, as thidiazuron is used at cotton harvest, typically after flowering, pollinators that are visiting off-site plants that are blooming at the time of the cotton harvest could be contaminated by spray drift from cotton fields and exposed to thidiazuron. For these reasons, this chemical will be subject to data call-ins for the full suite of pollinator studies. EPA is supportive of the NCC's research and educational efforts to minimize drift concerns. EPA and the Services are continuing to work together to further develop and refine methods to assess risk to listed species.

Comments submitted by the Center for Biological Diversity in EPA-HQ-OPP-2015-0381-0022.

2. Comment: *CBD opposes the continued registration of thidiazuron at this time because, they assert, the Agency has determined that thidiazuron has the potential to cause adverse effects to*

species. CBD's comments on the Proposed Interim Registration Review Decision for Thidiazuron focus on EPA's duty to initiate consultation with the Services prior to completion of the registration review process for thidiazuron. CBD states that the registration review of thidiazuron cannot be completed in compliance with EPA's obligations under both FIFRA and the ESA until the EPA concludes that the continued use of thidiazuron will have "no effect" on listed species or critical habitat, or completes consultation. CBD contends that there are readily available data and information sources that would allow EPA to complete Step 1 of the Interim Approaches for National Level Endangered Species Assessments Based on the Recommendations of the National Academy of Science. CBD provided specific label language to implement the Bulletins Live! System, stating that this label language would enable EPA to comply with current and continuing ESA duties. Lastly, they state that EPA must take a precautionary approach and enter into consultations with the Services on thidiazuron as outlined in the Interim Approaches document.

CBD also claims that although EPA is proposing to minimize spray drift, there is not substantial evidence to demonstrate that the proposed measures are sufficient for this chemical. The CBD states that the EPA must require in-field buffers. Furthermore, the comment from CBD claims that the Agency must prohibit tank mixtures unless the Agency is certain that they will not cause synergistic effects, and reminds the Agency that the General Accounting Office (GAO) advised EPA to evaluate the effects of mixtures of pesticides to bees.

Response: Thidiazuron is currently undergoing registration review. As provided in EPA's registration review regulations at 40 CFR section 155.56, EPA may, in its discretion, issue an interim decision before the completion of registration review when, among other things, it determines that it cannot complete registration review because additional information is necessary to complete the Agency's assessment. In addition, section 155.56 also provides that EPA may require risk mitigation measures in an interim decision. Consistent with this provision, EPA is issuing this interim registration review decision for thidiazuron in part so that it can move forward with aspects of the registration review decision that are complete while EPA continues to work with the Services on further developing, streamlining and implementing the interim approaches that will be used to complete its registration review of endangered species assessment for thidiazuron. EPA believes the public and the environment benefit from EPA's early action on the matters covered by this interim decision -- including risk mitigation, specifically adding spray drift mitigation language on product labels -- as described in Section IV of this document. EPA does not believe the ESA compels a contrary result. Taking early action to address some risks now serves to benefit the environment and does not preclude EPA from taking any additional necessary actions to address effects to listed species that EPA concludes are necessary as it works to complete registration review.

EPA plans to address CBD's concerns with the development of its final registration review decision. EPA anticipates initiating consultation with the Services after issuing the interim registration review decision, but prior to issuing the final registration review decision. This interim registration review decision, like the proposed interim decision, states that EPA is not making a complete endangered species finding, and that the Agency's final registration review decision for thidiazuron will depend upon the results of any necessary ESA Section 7 consultation with the Services, an assessment of non-target exposure to bees, as well as the results of a FFDCA Section 408 (p) endocrine screening.

EPA is still in the process of developing, streamlining and implementing the interim approaches based on the 2013 NAS Report recommendations, including Steps 1 and 2 of the Biological Evaluation for listed species. CBD's comments reference the available critical habitat; however, as CBD noted, not all species have critical habitat. Furthermore, critical habitat is just one piece of the species' range. EPA is working with the Services to ensure that it has the best available species range information for all listed species. We are also working collaboratively with the Services and USDA to further evaluate and refine the appropriate pesticide use footprint based on registered labeled use patterns. EPA and the Services will continue to refine the interim approaches based on stakeholder feedback from a June 2016 workshop as well as public comments received on the draft Biological Evaluations for chlorpyrifos, diazinon, and malathion and comments expected on the draft Biological Evaluations for carbaryl and methomyl in 2017. As a result, EPA expects to continue to develop and refine the interim approaches for Steps 1 and 2 through work on the pilot chemicals before completing Step 1 for thidiazuron.

CBD's comments also provided label language referring pesticide applicators to EPA's *Bulletins* System, and a statement that all product labels for thidiazuron must contain this language. However, since there are no Bulletins for thidiazuron, it is unnecessary at this point in time, to include this language on the label for thidiazuron. Inclusion of a reference to Bulletins on the product label when no Bulletins exist is likely to result in confusion for pesticide applicators and growers. However, EPA is in agreement with CBD that Bulletins are the appropriate mechanism to implement any necessary geographically-specific pesticide use limitations intended to protect listed species. EPA plans to use *Bulletins Live! Two* to implement any Bulletins that would be generated as we complete the evaluation of potential risks of thidiazuron to listed species and designated critical habitat.

EPA originally considered spray buffers for both ground and aerial application of thidiazuron on cotton to protect sensitive dicot plant species adjacent to cotton fields. However, upon further investigation of the incident data and the typical application rates for thidiazuron (the typical rates are much less than the 0.2 lb ai/A rate used in the risk assessment), as well as the potential impact to cotton growers, EPA determined that spray buffers were not necessary for thidiazuron. The thidiazuron registrants have agreed to various label changes designed to reduce off-target spray drift (see section IV). EPA has determined that implementing in-field buffers for thidiazuron would not have a great impact beyond the proposed mitigation, but could have a significant impact to growers using thidiazuron.

As we evaluate the data supporting a pesticide registration, Agency scientists look for indications of synergy. If there are data to indicate synergy for a formulated mixture, EPA evaluates the potential effects in our risk assessments. We are currently working with our federal partners to ensure our evaluation of synergy is as robust as possible. EPA's safety evaluations consider an extensive battery of exposure and toxicity data on each pesticide active and inert ingredient, as well as the formulated product, and exposure assessments assume the greatest potential exposure. The risk assessment process ensures that when a pesticide is used according to the label, people and the environment are adequately protected.

The Agency issued its Guidance for Assessing Pesticide Risks to Bees in 2014. For pesticide cases which opened prior to June 2014, the Agency may decide to: 1) require pollinator data consistent with the Guidance, or 2) determine pollinator data are not required based on available evidence that suggests there is an absence of potential risk (*i.e.,* low hazard and/or an absence of potential exposure). For pesticide cases which opened registration review after 2014, the Agency has incorporated the pollinator risk assessment framework and data requirements into its work plans upon docket openings for such chemical cases. For registration review cases where the Agency intends to require pollinator data, then an assessment of pollinator risk remains an outstanding component of that case. The Agency is currently determining a procedure to prioritize all chemicals that need data, and a timeline in which to issue a pollinator data call in for those cases. The registration review of thidiazuron opened in 2015 and, although available data indicate that thidiazuron is not very toxic to bees, exposure to pollinators cannot be precluded because cotton flowering is intermittent and some flower buds may still be open during thidiazuron application. Therefore, the Agency will require pollinator data for this case.

II. USE AND USAGE

Thidiazuron is a plant growth regulator registered for use as a pre-harvest defoliant in cotton. Thidiazuron contains a hormone known as a cytokinin. Very high concentrations of cytokinins enhance ethylene synthesis and ethylene promotes the defoliation of cotton. Thidiazuron reduces the foliage and immature fruiting structures which contribute to the staining of harvested cotton and facilitates cotton harvesting. Thidiazuron is not registered for any non-agricultural uses.

Thidiazuron is the third most used growth regulator on cotton in the U.S., with an average of 4 million cotton acres treated annually. It follows mepiquat chloride, the most frequently used growth regulator on cotton, and ethephon, the second most frequently used growth regulator on cotton. Nationally, approximately 80% of thidiazuron is applied by ground, and 20% is applied aerially. On average, approximately 284,000 lbs of thidiazuron are applied annually, with the most usage in top cotton producing states such as Georgia and Texas.

III. SCIENTIFIC ASSESSMENTS

A. Human Health Assessment

A summary of the Agency's human health risk assessment is presented below. The most updated Agency science policies and risk assessment methodologies were used to prepare a combined scoping document and risk assessment in support of the registration review of thidiazuron. This combined human health scoping document and draft human health risk assessment for registration review, titled, *Thidiazuron: Human Health Combined Scoping Document and Draft Risk Assessment for Registration Review*, was completed in June 2015. This document is located in the public docket (EPA-HQ-OPP-2015-0381), which can be accessed at http://www.regulations.gov/.

1. Human Health Risk Summary

Dietary Exposure Assessment

A revised dietary (food and drinking water) risk assessment was conducted. An acute dietary assessment was not performed because there were no acute adverse effects observed in available toxicology studies. The chronic dietary risk assessment was highly conservative, using tolerance level residues and 100% of crop treated assumptions. The chronic dietary (food and drinking water) estimated risks were below the Agency's level of concern (LOC) for the U.S. population and all population subgroups. The highest exposure and risk estimate was for children 1 to 2 years old which occupied 9.3% of the chronic population adjusted dose (cPAD) for thidiazuron. The PAD is the maximum acceptable dose of a substance adjusted to factor risks to certain population groups.

Residential Exposure Assessment

There are no residential uses of thidiazuron, therefore, a residential risk assessment was not completed. However, an assessment of potential residential exposures from spray drift from applications to cotton fields was completed since it may be a source of post-application exposure. The spray drift risk estimates are based on agricultural application scenarios representing the highest potential drift exposure combined with a screening level risk assessment approach based on modeled drift estimates and children's exposure (incidental oral + dermal) on lawns adjacent to a treated field. No dermal hazard was identified for thidiazuron, therefore no dermal MOEs were calculated. Children's (1 to < 2 year old) incidental oral risk estimates from indirect exposure to thidiazuron related to spray drift result in no risk concerns for any application scenario. Risk estimates from ground boom and aerial applications are not of concern at the field edge for all situations considered because margins of exposure (MOEs) ranged from 32,000 to 44,000, where the LOC is an MOE of 100. Therefore MOEs > 100 are not of concern.

Aggregate Exposure Assessment

Exposure from aggregate risks were considered from three major sources: food, drinking water, and residential exposures. Since there are no residential uses, an aggregate exposure assessment for thidiazuron includes consideration of exposures from food and drinking water. No aggregate risks were identified since exposure from food and drinking water were not of concern.

Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA requires the Agency to consider the cumulative effects of exposure to substances that have a common mechanism of toxicity. These considerations include the possible cumulative effects of such residues on infants and children.

EPA has not made a common mechanism of toxicity finding for thidiazuron and any other substances, and thidiazuron does not appear to produce a toxic metabolite produced by other substances. Therefore, EPA has not assumed that thidiazuron has a common mechanism of toxicity with other substances, and a cumulative effects assessment was not performed.

Occupational Exposure Assessment

The occupational risk assessment estimates risk to handlers (those who mix, load, and apply a pesticide) and to workers (those who re-enter a treated area to perform tasks) in an occupational setting via the dermal and inhalation routes of exposure. Risks were evaluated for thidiazuron use on cotton.

The Agency conducted occupational handler exposure and risk assessments for all registered uses. Short- and intermediate-term MOEs for handlers were not of concern to the Agency because they exceeded the target MOE of 100. Inhalation MOEs for the occupational handler assessment range from 33,000 to 1,500,000. No dermal hazard was identified for thidiazuron, therefore no dermal MOEs were calculated.

EPA uses the term post-application to describe exposures that occur when individuals are present in an environment that has been previously treated with a pesticide (also referred to as re-entry exposure). No dermal hazard was identified for thidiazuron, therefore, a dermal post-application risk assessment was not completed. Due to thidiazuron's low dermal and inhalation toxicity, a restricted entry interval (REI) of 12 hours was found adequate to protect agricultural workers from post-application exposures to thidiazuron. The current REI on the labels is 24 hours, but this will be changed to 12 hours.

Post-application inhalation exposure is possible through volatilization. Even though thidiazuron is not expected to be volatile, EPA completed a qualitative analysis to be protective. EPA relied on handler inhalation risk estimates to determine possible post-application risks from volatilization. This is because handler exposure is likely to result in higher exposure than post-application exposure. Since handler inhalation risk estimates were not of concern, post-application inhalation exposure is also not of concern.

2. Human Incidents

For this registration review, a human incident search was conducted in February 2015. One incident was reported in the OPP Incident Data System (IDS) from January 1, 2010 to December 30, 2014. Sixteen incidents were reported in the CDC/NIOSH's Sentinel Event Notification System for Occupational Risks (SENSOR) from 1998 to 2010. All incidents were of low severity. Based on the low frequency and severity of cases involving thidiazuron reported in both IDS and SENSOR, there does not appear to be a concern at this time that would warrant further investigation. The Agency will continue to monitor the incident information. For additional details, please refer to the *Thidiazuron: Tier I Review of Human Incidents* in docket EPA-HQ-OPP-2015-0381, which can be accessed at www.regulations.gov.

3. Tolerances

Tolerances are established in 40 CFR §180.403 for residues of thidiazuron in/on cotton and livestock commodities. The tolerance expression for plant and livestock commodities needs to be modified to reflect the current standards for tolerance expression. A new tolerance for cotton hulls is recommended. Changes to the tolerance levels for cotton (un-delinted seed) and cotton gin byproducts are recommended. These changes are detailed in the document titled

Thidiazuron: Human Health Combined Scoping Document and Draft Risk Assessment for Registration Review. D424978, available in the public docket EPA-HQ-OPP-2015-0381, at www.regulations.gov. EPA intends to modify the tolerances for thidiazuron.

4. Human Health Data Needs

The human health database for thidiazuron is mostly complete. Radio-validation data for the tolerance enforcement method (TU-002-A06-01) in livestock commodities is still needed. The following reference standards need to be submitted to EPA's National Pesticide Standards Repository: phenylurea and 4-hydroxy-thidiazuron.

B. Environmental Assessment

The summary of the Agency's environmental risk assessment for thidiazuron is presented below. The most updated Agency science policies and risk assessment methodologies were used to prepare a combined problem formulation and risk assessment document in support of the registration review for thidiazuron. This joint problem formulation and draft risk assessment for the environmental fate, ecological risk, and endangered species for registration review, titled, *Registration Review: A Joint Problem Formulation and Draft Risk Assessment of the Environmental Fate and Ecological Risk of Thidiazuron*, was completed in June 2015. This document is located in the public docket EPA-HQ-OPP-2015-0381, at www.regulations.gov.

No risks were identified for most taxa. Potential risks were identified for non-target terrestrial plants, particularly dicots, and birds (also surrogates for terrestrial-phase amphibians and reptiles) from chronic drinking water risk.

The Agency also completed a screening-level listed species assessment for thidiazuron, and identified potential risks to listed terrestrial plants and listed species of plant-dependent taxa. The Agency is currently working with its federal counterparts, and other stakeholders to implement an interim approach for assessing potential risk to listed species and their designated critical habitats. Once the scientific methods necessary to complete risk assessments for listed species and their designated critical habitats are finalized, the Agency will complete an endangered species assessment for thidiazuron. As such, only screening-level risks to listed species are identified at this time. In a screening-level analysis the Agency uses reasonable worst-case scenarios and conservative assumptions to be protective.

1. Environmental Fate and Exposure

In soil, thidiazuron is persistent, as shown by environmental fate data. It has intermediate mobility in soil. In surface water, photolysis is expected to be the major route of transformation.

The major degradates of thidiazuron include photoproduct I (photothidiazuron), photoproduct II (phenylurea), and thiazoylurea. Photothidiazuron (photoproduct I) is a structural

isomer of the parent, and photoproduct II has a substantially altered chemical structure. Based on its solubility and vapor pressure (Henry's law), thidiazuron is non-volatile.

Based on its relatively low n-octanol/water partitioning coefficient, thidiazuron is not expected to bioconcentrate.

2. Risk Conclusions

No changes to the use pattern of thidiazuron have occurred since the RED was issued in 2005. EPA updated its 2005 RED ecological risk assessment for thidiazuron to include exposure routes/taxa that were not previously assessed. The taxa and routes of exposure assessed in 2005 were: acute and chronic risk to freshwater fish/invertebrates, acute exposure to estuarine/marine fish and invertebrates, exposure to aquatic nonvascular and vascular plants, acute exposure to birds and mammals, and exposure to terrestrial plants. The 2005 RED ecological risk assessment did not identify risk concerns to any taxa except to non-target terrestrial and semi-aquatic dicots and possible chronic risks to mammals. Please refer to the 2005 RED ecological risk assessment titled *Environmental Fate and Effects Division's Phase 2 Risk Assessment for the Reregistration Eligibility Decision of Thidiazuron for Use on Cotton*, located in docket EPA-HQ-OPP-2015-0381, at www.regulations.gov, for a listing of risks to taxa not outlined here.

The Agency has also completed a screening-level endangered species risk assessment. Updated risks for thidiazuron are outlined in the following sections (including screening-level risks to listed species).

Birds/Terrestrial-Phase Amphibians and Reptiles

Avian acute oral and dietary studies did not show adverse effects at the highest test doses. The highest chronic avian risk quotient (RQ) was 0.23, which is below the chronic LOC of 1.0. Overall, the potential risk for adverse effects on survival, reproduction, and growth to bird species that inhabit treated fields and forage on vegetation and insects with thidiazuron residues is expected to be low. However, the only potential pathway of concern for birds is for those exposed to drinking water containing residues of thidiazuron on a chronic basis, as indicated by the Screening Imbibition Program (SIP). Exposure to thidiazuron via inhalation was determined to not be a potential pathway of concern for birds on an acute exposure basis.

EPA currently uses surrogate data (birds) to estimate risks for terrestrial-phase amphibians and reptiles when taxa-specific data are not available. There were no LOC exceedances for birds via oral and dietary routes; these findings also apply to terrestrial-phase amphibian and reptiles. Overall, the potential risk for adverse effects on survival, reproduction and growth to terrestrial-phase amphibians and reptiles that inhabit treated fields foraging on vegetation and insects with thidiazuron is expected to be low. As with birds, there is a potential pathway of concern for terrestrial-phase amphibians and reptiles exposed to drinking water alone on a chronic basis.

Mammals

Both dietary and dose-based RQ values do not exceed the chronic risk level of concern (LOC = 1) for all size classes of mammals that consume short grass, tall grass, broadleaf plants, fruits, seeds and pods, and arthropods. The highest chronic dietary-based RQ was 0.17. The highest dose-based chronic RQ was 0.83.

Overall, the potential risk for adverse effects on survival, reproduction, and growth to mammals that inhabit thidiazuron-treated fields is anticipated to be low. There is no concern for mammals exposed to drinking water alone contaminated with thidiazuron or via inhalation of thidiazuron.

Terrestrial Invertebrates (Pollinators)

Acute honey bee data, from Tier I studies, were available and used to generate acute non-definitive endpoints and RQs. The highest acute non-definitive RQ was 0.06, which is below the acute dietary LOC of 0.4. However, chronic dietary risk to adult honey bees, and acute and chronic dietary risk to larval honey bees is uncertain due to lack of data. Because thidiazuron is used at cotton harvest, long after flowering, it is not likely to cause exposure to pollinators visiting cotton plants. However, pollinators visiting off-site plants that are contaminated by spray drift from cotton fields may be exposed to thidiazuron. Acceptable toxicity data to honey bee adults and larvae have not been submitted for thidiazuron and these data are needed to fulfill EPA's recent policy on pollinator protection. A more complete pollinator screening for thidiazuron is needed in the future. The Agency is requiring additional pollinator data to complete a pollinator risk assessment.

Terrestrial Plants

In general, monocots are less sensitive to thidiazuron than dicots. The highest listed terrestrial plant RQ was 13 for listed dicots located in semi-aquatic areas adjacent to treated fields (from a combination of runoff and spray drift exposure). The highest non-listed plant RQ was 3.5.

Spray drift is the main driver of terrestrial plant risk. Spray drift RQs were calculated for both listed and non-listed terrestrial plants at varying droplet sizes for both ground and aerial modes of application based on endpoints selected from the most sensitive species, lettuce. In general, spray drift RQs were higher for listed plants compared to non-listed plants. RQs were higher for aerial application compared to ground application. RQs were lower at coarser droplet sizes compared to finer droplet sizes. For ground application to non-listed plants, RQs exceed the LOC of 1 at 300 ft from the edge of the field for very fine to fine droplet sizes, and exceed the LOC at 100 ft from the edge of the field at fine to medium/coarse droplet sizes. For listed plants, ground spray drift RQs exceeded the LOC at the limit of the model (approximately 1,000 ft from the edge of the field) for all droplet sizes. For aerial application to non-listed plants, RQs exceed the LOC at 500 ft from the edge of the field at coarse to very coarse droplet sizes, and exceed the LOC at the limit of the model (1,000 ft from the edge of the field) at fine to medium droplet sizes. For aerial application to listed plants, RQs exceed the LOC at 1,000 ft from the edge of the field for all droplet sizes.

Spray drift RQs were not of concern for other terrestrial plant species tested, except cucumber (the second-most sensitive species tested), where the RQ exceeds the listed plant LOC at 250 ft from the edge of the field. The RQ is below the LOC at 328 ft from the edge of the field.

Estuarine/Marine Fish and Invertebrates

Chronic RQs were not available in past assessments for estuarine/marine fish and invertebrates due to lack of data. As a result, EPA used the Acute-to-Chronic Ratio (ACR) method to calculate chronic RQs for estuarine/marine fish and invertebrates using available data. Using this method, the chronic RQs for estuarine/marine fish and invertebrates are <0.01 and 0.03, respectively, both of which are below the chronic LOC of 1.0.

Thus, thidiazuron exposures and risks to estuarine/marine fish and invertebrates on a chronic basis are expected to be minimal. Together with other aquatic organisms, the potential risk for adverse effects on survival, reproduction, and growth to fish and invertebrates that inhabit freshwater and estuarine waters with thidiazuron residues (as a result of surface runoff and spray drift from adjacent treated fields) is expected to be low.

3. Ecological Incidents

As of April 2015, there are four reported incidents for thidiazuron in the Ecological Incident Information System (EIIS). The dates of the incident reports range from 1996 to 2009. The reports involve two incidents of damage to lettuce via spray drift and one incident of damage to ryegrass by treating directly. The lettuce incidents involve one misuse where 150 acres of lettuce were damaged and one registered use where 53 acres of lettuce were damaged. The ryegrass incident involved damage to 75 acres. One incident involves accidental misuse and chicken mortality. The chicken incident is also reported in the Avian Information Monitoring System (AIMS). For additional details, please refer to the document titled *Registration Review: A Joint Problem Formulation and Draft Risk Assessment of the Environmental Fate and Ecological Risk of Thidiazuron*, dated June 16, 2015, located in docket EPA-HQ-OPP-2015-0381, at www.regulations.gov.

4. Ecological Effects Data Needs

The Agency identified several data gaps for thidiazuron in its ecological risk assessment. EPA proceeded with a registration review ecological risk assessment, a proposed interim registration review decision, and now this interim registration review decision even with these data gaps because it felt confident that risks from the use of thidiazuron on cotton were not being underestimated. The existing database at the time of risk assessment was adequate to understand the fate and effects of thidiazuron. However, the following data gaps will help complete the existing database for thidiazuron:

- Guideline 835.6100—Terrestrial Field Dissipation study (storage stability portion only)[1]

[1] A freezer storage stability study was submitted (MRID 44450701) but has not been reviewed. EPA will review this study and modify the list of data requirements as necessary.

- Guideline 850.2100—Avian acute oral toxicity (with passerine species)
- Guideline 850.3040—Field testing for pollinators (tier III)
- Guideline 850.6100—Enforcement Analytical Method for Water
- Guideline 850.6100—Enforcement Analytical Method for Soil[2]
- Non-guideline—Honey bee larval acute oral toxicity (tier I)
- Non-guideline—Honey bee adult 10-day chronic oral toxicity (tier I)
- Non-guideline—Honey bee larval chronic oral toxicity (tier I)
- Non-guideline—Field trial of residues in pollen and nectar (tier II)
- Non-guideline—Semi-field testing for pollinators—tunnel or colony feeding (tier II)

EPA plans to issue a DCI for these data.

5. Endangered Species Assessment

In November 2013, the EPA, along with the Services and the USDA, released a summary of their joint Interim Approaches for assessing risks to listed species from pesticides. The Interim Approaches[3] were developed jointly by the agencies in response to the National Academy of Sciences' (NAS) report recommendations, and reflect a common approach to risk assessment shared by the agencies as a way of addressing scientific differences between the EPA and the Services. The NAS report[4] outlines recommendations on specific scientific and technical issues related to the development of pesticide risk assessments that EPA and the Services must conduct in connection with their obligations under the ESA and FIFRA.

The joint Interim Approaches were released prior to a stakeholder workshop held on November 15, 2013. In addition, the EPA presented the joint Interim Approaches at the December 2013 Pesticide Program Dialogue Committee (PPDC) and State-FIFRA Issues Research and Evaluation Group (SFIREG) meetings. The agencies also held stakeholder workshops in April and October 2014, in April 2015, and in June of 2016, allowing additional opportunities for stakeholders to comment on the Interim Approaches. Additional workshops are planned to enhance stakeholder involvement. As part of a phased, iterative process for developing the Interim Approaches, the agencies will also consider public comments on the Interim Approaches in connection with the development of upcoming registration review decisions. The details of the joint Interim Approaches are contained in the white paper *Interim Approaches for National-Level Pesticide Endangered Species Act (ESA) Assessments Based on the Recommendations of the National Academy of Sciences April 2013 Report*[5], dated November 1, 2013.

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[2] A method for soil (MRID 41987102) was submitted but has not been reviewed. EPA will review this study and modify the list of data requirements as necessary.

[3] *Interim Approaches for National-Level Pesticide Endangered Species Act (ESA) Assessments Based on the Recommendations of the National Academy of Sciences April 2013 Report.* Available at http://www2.epa.gov/endangered-species/interim-approaches-pesticide-endangered-species-act-assessments-based-nas-report

[4] *Assessing Risks to Endangered and Threatened Species from Pesticides*. National Academy of Sciences. 2013. Available from http://www.nap.edu/catalog.php?record_id=18344

[5] Available at https://www.epa.gov/endangered-species/implementing-nas-report-recommendations-ecological-risk-assessment-endangered-and

Given that the agencies are continuing to develop and work toward implementation of the Interim Approaches to assess the potential risks of pesticides to listed species and their designated critical habitat, the ecological risk assessment supporting this interim registration review decision for thidiazuron does not contain a complete ESA analysis that includes effects determinations for specific listed species or designated critical habitat. Although EPA has not yet completed effects determinations for specific species or habitats, for this interim decision, EPA's evaluation assumed, for all taxa of non-target wildlife and plants, that listed species and designated critical habitats may be present in the vicinity of the application of thidiazuron. This assessment allows EPA to focus its future evaluations on the types of species where the potential for effects exists once the scientific methods being developed by the agencies have been fully vetted. Once the Agencies have fully developed and implemented the scientific methodology for evaluating risks for listed species and their designated critical habitats, these methods will be applied to subsequent analyses for thidiazuron as part of completing the final registration review decision.

C. Endocrine Disruptor Screening Program

As required by FIFRA and FFDCA, EPA reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, subchronic and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints which may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, EPA evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups. As part of its most recent registration decision for thidiazuron, EPA reviewed these data and selected the most sensitive endpoints for relevant risk assessment scenarios from the existing hazard database. However, as required by FFDCA section 408(p), thidiazuron is subject to the endocrine screening part of the Endocrine Disruptor Screening Program (EDSP).

EPA has developed the EDSP to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance, and establish a dose-response relationship between the dose and the E, A, or T effect.

Under FFDCA section 408(p), the Agency must screen all pesticide chemicals. Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. A second list of

chemicals identified for EDSP screening was published on June 14, 2013[6] and includes some pesticides scheduled for registration review and chemicals found in water. Neither of these lists should be construed as a list of known or likely endocrine disruptors. Thidiazuron was not on list 1 or list 2. For further information on the status of the EDSP, the policies and procedures, the lists of chemicals, future lists, the test guidelines and the Tier 1 screening battery, please visit our website[7].

In this interim decision, EPA is making no human health or environmental safety findings associated with the EDSP screening of thidiazuron. Before completing this registration review, the Agency will make an EDSP FFDCA section 408(p) determination.

IV. RISK CHARACTERIZATION and INTERIM REGISTRATION REVIEW DECISION

A. Ecological Risk Characterization for Non-Listed Species

EPA has estimated potential risks for birds, terrestrial-phase amphibians and reptiles (from drinking water) and non-target terrestrial plants (mainly from spray drift). In a screening-level analysis the Agency uses reasonable worst-case scenarios and conservative assumptions to be protective. Environmental exposure and risk can vary greatly with numerous other factors. As a result, environmental risk can be difficult to represent either as a single number (RQ) or even as a RQ range. Below is a brief discussion of several, but not all, of the factors that can affect both the magnitude and/or the frequency of risk that may be associated with the use of thidiazuron.

Birds, Terrestrial-Phase Amphibians and Reptiles

The ecological risk assessment identified a potential pathway of concern for birds, terrestrial-phase amphibians and reptiles exposed only to drinking water containing residues of thidiazuron on a chronic basis, as indicated by SIP modeling. However, SIP is a conservative screening model that assumes that thidiazuron would be present in water at its solubility limit (31 mg/L), that 100% of drinking water needs are obtained from that source, and that the most sensitive bird is exposed. Based on information on how thidiazuron partitions between water and soil (median desorption coefficient is 11.8 L/kg), EPA estimates that an equivalent of 0.05 mg/L thidiazuron would be available in water after an application of thidiazuron at the maximum application rate (0.21 lb ai/A). This amount is well below the maximum amount of thidiazuron that can be dissolved in water (the solubility limit of 31 mg/L) which EPA assumed for SIP modeling. EPA also ran the SIP model at half the solubility limit (15 mg/L) of thidiazuron and the model did not indicate a pathway of concern. Given this consideration, risk to birds, terrestrial-phase amphibians, and reptiles is not likely to be of concern (emails from EFED dated March 31, 2016 and December 15, 2015, located in docket EPA-HQ-OPP-2015-0381 at www.regulations.gov).

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[6] See http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0477-0074 for the final second list of chemicals

[7] http://www.epa.gov/endo/

Terrestrial Plants

The ecological risk assessment identified risk to non-target terrestrial plants (from mostly spray drift). However, the magnitude of the risk to terrestrial plants may be over-estimated due to the fact that the maximum single application rate of 0.2 lb ai/A was assessed for both ground and aerial application to cotton. In practice, information available to the Agency indicates that growers apply an average of 0.066 lbs ai/A in a single application. This is less than half the application rate that was assessed. Growers may use multiple applications of thidiazuron in cases where there are dense canopies, or if a high number of green bolls need to be opened. Up to three applications of thidiazuron may be applied in one year, and the seasonal rate for acres treated three times average 0.145 lb ai/A/year. Since this seasonal rate is less than the 0.2 lb ai/A assessed in the ecological risk assessment, risks to non-target terrestrial plants are likely lower in magnitude than estimated. For a more complete description of single and seasonal application rates for thidiazuron, please see the document titled *Thidiazuron Usage and Benefits Information (PC#120301)*, located in the docket EPA-HQ-OPP-2015-0381, at www.regulations.gov.

B. Characterizations of Benefits

Thidiazuron is an important tool in cotton production; 30 percent of the total cotton acreage is treated with thidiazuron annually. Cotton growers may prefer it because of its low toxicity, and its mode of action as a hormonal defoliant. Compared to other herbicidal defoliants, thidiazuron confers several benefits such as improved harvesting efficiency and improved boll quality. Use of herbicidal defoliants may result in desiccation instead of defoliation, and desiccation leaves leaf trash in harvested cotton. Compared to other defoliants, thidiazuron has also been shown to prevent regrowth, which may ease cotton harvesting. EPA also considered thidiazuron in relation to alternative cotton defoliants, such as mepiquat chloride, ethephon, tribufos, carfentrazone-ethyl, pyraflufen-ethyl, and paraquat dichloride. In most cases, thidiazuron is less toxic to all taxa than these alternative cotton defoliants (except for mepiquat chloride). Compared to mepiquat chloride, thidiazuron has greater toxicity to terrestrial dicots, but risks are otherwise comparable. The Agency believes that the use of thidiazuron may be a valuable alternative for certain pesticide users. Because of these characteristics, the use of thidiazuron among other conventional pesticide products may be considered a benefit. For more benefits and usage information for thidiazuron, please see the documents titled *Thidiazuron Usage and Benefits Information (PC # 120301)* and the *BEAD Chemical Profile (BCP) for Registration Review: Thidiazuron (120301)*, both accessible in the docket EPA-HQ-OPP-2015-0381, at www.regulations.gov.

C. Risk Mitigation Measures

In evaluating potential risk mitigation for thidiazuron, EPA considered the risks, the benefits, and the use pattern of this compound. EPA believes that there is potential risk to non-target plants (especially dicots) from the use of thidiazuron. However, these risks may be outweighed by the potential benefits associated with use of this compound.

Potential risks to non-target terrestrial plants may be lowered by reducing spray drift. The Agency is encouraging the development of pesticide drift reduction technologies (or DRTs[8]) that will help realize user, societal, and environmental benefits including:

- reducing the loss of pesticide from the application site,
- reducing pesticide exposures to people, wildlife, and the environment, and
- reducing risks of damage and liabilities from off-target deposition of drift.

Furthermore, EPA believes that the use of proven DRTs will provide users with a wider range of options for addressing drift concerns. Such DRTs could include specialized nozzles, spray shields, and drift-reducing adjuvant chemicals. The Agency encourages users, producers of thidiazuron, and related industries to develop, consider, test, and use these types of innovations as part of the risk management plan for thidiazuron. DRTs are expected to be useful in mitigating the risks drift poses to non-target species, and particularly in addressing risks to listed species.

With a view towards reducing spray drift risk, the Agency engaged the technical registrants of thidiazuron to develop label language to reduce spray drift, as well as to provide clarity and consistency across thidiazuron labels. These measures are also expected to reduce potential exposure to listed plant species as well as non-target plants adjacent to treated fields.

Label changes

1. Required Language for Thidiazuron Product Labels

The Agency initiated discussions with the technical registrants of thidiazuron (Nufarm Limited, Bayer Cropscience, Adama Celsius Property B.V., Arysta Lifescience North America, LLC, and Loveland Products) to discuss potential label updates. The initial set of draft proposed label changes and notes from this discussion are available in the public docket EPA-HQ-OPP-2015-0381, which can be accessed at www.regulations.gov. EPA originally considered spray buffers for both ground and aerial application of thidiazuron on cotton to protect sensitive dicot plant species adjacent to cotton fields. However, upon further investigation of the incident data and the typical application rates for thidiazuron (the typical rates are much less than the 0.2 lb ai/A rate used in the risk assessment), as well as the potential impact to cotton growers, EPA determined that spray buffers were not needed. The thidiazuron registrants have agreed to various label changes designed to reduce off-target spray drift (see below). EPA has determined that implementing in-field buffers for thidiazuron would not have a great impact beyond the proposed mitigation, but could have a significant impact to growers using thidiazuron. The following label changes are intended to further reduce risk to non-target plants from use of thidiazuron:

"Use a nozzle that produces medium spray or coarser spray according to ASABE (ANSI/ASAE) standard S572.1 MAR2009 for both ground and aerial application."

"When applying aerially:

[8] http://www.epa.gov/reducing-pesticide-drift/about-drift-reduction-technology-program

- *Do not release spray at a height greater than 10 ft above the crop canopy, unless a greater application height is necessary for pilot safety.*
- *The spray boom must be mounted on the aircraft so as to minimize drift caused by wing tip or rotor blade vortices. The boom length must not exceed 75% of the wingspan or 90% of the rotor blade diameter.*
- *When applying to crops via aerial application equipment, use ½ swath displacement upwind at the downwind edge of the field.*
- *Nozzles must be oriented so the spray is directed toward the back of the aircraft."*

"When using ground application equipment, apply with nozzle height no more than 2 feet above the ground or crop canopy."

"*For both aerial and ground application, do not apply when wind speeds exceed 10 miles per hour at the application site.*"

"*Do not spray via ground or aerial application equipment during temperature inversions.*"

"Mixtures with organophosphates can increase non-target crop phytotoxicity."

"Some crops (e.g., citrus, lettuce, cantaloupes, and others) are sensitive to this chemical and additional care needs to be exercised if these crops are present in adjacent fields."

The label changes described above are mandatory, enforceable statements and will supersede any existing language already on product labels (either advisory or mandatory) covering the same topics. The Agency is also requiring that the registrants add certain advisory language on all thidiazuron product labels. Registrants will need to ensure that any existing advisory language left on labels does not contradict or modify the new mandatory spray drift statements. The Agency is also requiring that all references to volumetric mean diameter (VMD) information for spray droplets be removed from all thidiazuron labels where such information currently appears. The new language specified above, cites ASABE S572.1, eliminates the need for the VMD information because the droplet size category is easier to recognize and understand for the user.

2. Advisory Language for Thidiazuron Product Labels

In addition to enforceable spray drift mitigation language, EPA is proposing additional advisory statements to address a variety of potential ecological concerns. The categories of advisory language include spray drift mitigation, pollinator protection, and runoff prevention. EPA is requiring that all thidiazuron labels adopt consistent advisory text, which can be found in Appendix C.

Spray Drift Mitigation Advisory Language

The enforceable drift statements required in this interim decision will directly impact the amount of drift that could result from applications of thidiazuron, but will not eliminate exposure to non-target species. Therefore it will be beneficial to users to have additional information about drift that could influence the choices they make at the time of application. EPA is

requiring advisory spray drift language on labels to help guide users in making applications using the best techniques to reduce drift. In order to help differentiate the enforceable text from the advisory text, EPA is requiring that these statements be separated on the labels and that enforceable text be placed within a spray drift box.

Pollinator Advisory Language

As mentioned above, some of the advisory language concerns potential risks to pollinators. The protection of pollinating organisms is a priority for the Agency. Currently available data suggest that using thidiazuron does not directly impact the health of adult pollinators. However, it is possible that spray drift and runoff from thidiazuron applications may negatively impact the forage and habitat of pollinators. EPA is therefore requiring pollinator protection advisory language.

Runoff Prevention Advisory Language

As noted previously, there are both spray drift and runoff concerns from thidiazuron applications. Furthermore, these two exposure pathways of spray drift and runoff could potentially coincide, resulting in greater exposure and, therefore, greater expected adverse effects. While the Agency is focusing on mitigation measures for thidiazuron designed to reduce spray drift rather than runoff, EPA is also requiring a weather advisory statement that is anticipated to help reduce risks from runoff.

3. Label Consistency

Certain labeling elements, such as the formulation type and pounds of active ingredient (ai) per gallon of product, is required to be added to all thidiazuron labels that do not already contain this information. Guidance on the list of elements proposed to be included on all thidiazuron labels can be found in Appendix D: Information to Be Provided on All Thidiazuron Product Labels.

D. Interim Registration Review Decision

EPA has completed a quantitative human health risk assessment, and a quantitative ecological risk assessment, including a screening-level endangered species analysis of thidiazuron. The Agency determined that there are no human health risks of concern. The Agency also determined that there are no ecological risks of concern, except for non-target terrestrial plants.

Consistent with EPA's June 2014 *Guidance for Assessing Pesticide Risks to Bees*[9], EPA is requiring pollinator data where applicable. EPA will issue a DCI to obtain these data for thidiazuron. In the near future, EPA will provide further information and guidance on this effort. The pollinator studies that could be required are included in Appendix A. The Agency will require data it believes are needed to help inform the pollinator risk assessment for thidiazuron.

In accordance with 40 CFR Sections 155.56 and 155.58, the Agency is issuing this *Thidiazuron Interim Registration Review Decision*. Except for the EDSP, ESA, and pollinator

[9] http://www2.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf

components of this case, the Agency has made the following interim registration review decision for thidiazuron:

- The Agency has not identified any human health risks of concern from the use of pesticide products that contain thidiazuron.
- The Agency has identified additional data requirements to further inform its understanding of thidiazuron (see Appendix A). EPA plans to issue a DCI for these data needs.
- Certain tolerance amendments are necessary for thidiazuron.
- The Agency has identified potential risk to sensitive dicots from thidiazuron, and is requiring certain changes to thidiazuron labeling to reduce potential risk from spray drift. These label changes are detailed in section IV.C of this document.

In this interim registration review decision, EPA is making no human health or environmental safety findings associated with the EDSP screening of thidiazuron, risk to pollinators, nor is it making a complete endangered species finding. The Agency's final registration review decision for thidiazuron will be issued once an effects determination for listed species is made, and ESA Section 7 consultation with the Services has taken place, if necessary; an EDSP FFDCA section 408(p) determination has been made; and a pollinator risk assessment has been completed.

V. NEXT STEPS AND TIMELINE

A. Interim and Final Registration Review Decisions

A Federal Register Notice will announce the availability of this *Thidiazuron Interim Registration Review Decision* in the thidiazuron registration review docket, (EPA-HQ-OPP-2015-0381), available at www.regulations.gov. EPA will make a final registration review decision for thidiazuron after an effects determination for listed species has been made, and ESA Section 7 consultation with the Services has taken place, if necessary; a pollinator risk assessment has been completed; and an EDSP FFDCA section 408(p) determination has been made. A summary of the planned data requirements are described in Appendix A, and a summary of the mitigation measures are described in Appendix B. All registrants with products containing thidiazuron must implement the specified label changes summarized in Appendix C and D within 60 days of issuance of this interim registration review decision.

Appendix A. Summary of Planned Data Requirements for Thidiazuron

Guideline	Study
835.6100	Terrestrial field dissipation (storage stability component only)[10]
850.2100	Avian acute oral toxicity (with passerine species)
850.3040	Field testing for pollinators (tier III)[11]
850.6100	Enforcement analytical method for water
850.6100	Enforcement analytical method for soil[12]
Non-guideline	Honey bee larval acute oral toxicity (tier I)
Non-guideline	Honey bee adult 10-day chronic oral toxicity (tier I)
Non-guideline	Honey bee larval chronic oral toxicity (tier I)
Non-guideline	Field trial of residues in pollen and nectar (tier II)[11]
Non-guideline	Semi-field testing for pollinators—tunnel or colony feeding (tier II)[11]

[10] A freezer storage stability study was submitted (MRID 44450701) but has not been reviewed. EPA will review this study and modify the list of data requirements as necessary.
[11] The need for tier II and tier III testing for pollinators will be determined based upon tier I tests and/or other lines of data and the need for a refined pollinator risk assessment.
[12] A method for soil was submitted (MRID 41987102) but has not been reviewed. EPA will review this study and modify the list of data requirements as necessary.

Appendix B: Summary of Risk Mitigation for Thidiazuron

Registration Review Case #: 4092 PC Code: 120301
Chemical Type: plant growth regulator Chemical Family: phenylurea
Mode of Action: plant defoliation by cytokinin release

Affected Population(s)	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Mitigation
✓Birds ✓Reptiles ✓Land-phase amphibians	✓ Drinking water	✓ Ingestion	✓Chronic	✓Pathway of concern for chronic drinking water exposure	No risk mitigation necessary. Chronic drinking water risks to birds, terrestrial reptiles, and terrestrial amphibians unlikely due to conservative assumptions used in SIP screening.
✓Terrestrial plants	✓ Spray drift ✓ Soil ✓ Runoff	✓ Translocation into plant parts ✓ Root uptake	✓Short-term ✓Long-term	✓Spray drift ✓Runoff	Spray drift management language and label advisories

Affected Population(s)	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Mitigation
Terrestrial plants	Runoff, spray drift	Systemic direct contact, water	Short-term Long-term	Short-term Long-term	Spray drift management measures: use of medium or coarser spray droplet sizes; ground application with nozzle height no more than 2 ft above canopy; no application when wind speeds exceed 10 mph; aerial spray application no more than 10 ft above crop canopy; no application during temperature inversions; ½ swath displacement upwind at the edge of the field for aerial application; boom length must not exceed 75% of the wingspan or 90% of the rotor blade diameter when applying via aerial application equipment Label advisories: exercise care when sensitive crops nearby; mixtures can increase phytotoxicity

Appendix C: Thidiazuron Label Table

Summary of Required Labeling Changes for Thidiazuron Uses		
Description	Required Amended Labeling Language for Thidiazuron Use Products	Placement on Label
End Use Products		
Spray Drift Management	*"Use a nozzle that produces medium spray or coarser spray according to ASABE (ANSI/ASAE) standard S572.1 MAR2009 for both ground and aerial application."*	Directions for Use
Spray Drift Management	*"When using ground application, apply with nozzle height no more than 2 feet above the ground or crop canopy."*	Directions for Use
Spray Drift Management	"*For both aerial and ground application, do not apply when wind speeds exceed 10 miles per hour at the application site.*"	Directions for Use
Spray Drift Management	"*Do not spray via ground or aerial application equipment during temperature inversions.*"	Directions for Use
Spray Drift Management	*"When applying aerially:* • *Do not release spray at a height greater than 10 ft above the crop canopy, unless a greater application height is necessary for pilot safety.* • *The spray boom must be mounted on the aircraft so as to minimize drift caused by wing tip or rotor blade vortices. The boom length must not exceed 75% of the wingspan or 90% of the rotor blade diameter.* • *When applying to crops via aerial application equipment, use ½ swath displacement upwind at the downwind edge of the field.* • *Nozzles must be oriented so the spray is directed toward the back of the aircraft."*	Directions for Use

Spray Drift Management	*Additional Required Labelling Action:* *-Registrants must remove information about volumetric mean diameter from all labels where such information currently appears.*	Directions for Use
Mixing Advisory	*"Mixtures with organophosphates can increase non-target crop phytotoxicity."*	Use Precautions and Restrictions
Restricted Entry Interval	*"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours."*	Agricultural Use Requirements
Non-target Crop Advisory	*"Some crops (e.g., citrus, lettuce, cantaloupes, and others) are sensitive to this chemical and additional care needs to be exercised if these crops are present in adjacent fields."*	Use Precautions and Restrictions
Advisory Spray Drift Management Language for all products that allow aerial or ground boom applications	*"**SPRAY DRIFT ADVISORIES*** *The interaction of many equipment and weather-related factors determines the potential for spray drift. The applicator is responsible for considering all these factors when making application decisions.* ***IMPORTANCE OF DROPLET SIZE*** *The most effective way to reduce drift potential is to apply large droplets. The best drift management strategy is to apply the largest droplets that provide sufficient coverage and control. The presence of sensitive species nearby, the environmental conditions, and pest pressure may affect how an applicator balances drift control and coverage. APPLYING LARGER DROPLETS REDUCES DRIFT POTENTIAL, BUT WILL NOT PREVENT DRIFT IF APPLICATIONS ARE MADE IMPROPERLY OR UNDER UNFAVORABLE ENVIRONMENTAL CONDITIONS! See Wind, Temperature and Humidity, and Temperature Inversions sections of this label.* ***Controlling Droplet Size – Ground Boom (note to registrants:** remove if ground boom is prohibited on product labels)*	Directions for Use

	• *Volume – Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger volumes.* • *Pressure – Use the lower spray pressures recommended for the nozzle. Higher pressure reduces droplet size and does not improve canopy penetration. WHEN HIGHER FLOW RATES ARE NEEDED, USE A HIGHER-CAPACITY NOZZLE INSTEAD OF INCREASING PRESSURE.* • *Nozzle Type – Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low-drift nozzles.* ***Controlling Droplet Size – Aircraft (note to registrants:** remove if aerial is prohibited on product labels)* • *Number of Nozzles – Use the minimum number of nozzles with the highest flow rate that provide uniform coverage.* • *Nozzle Orientation – Orienting nozzles so that the spray is emitted backwards, parallel to the airstream with produce larger droplets than other orientations. AVOIDING SPRAY DRIFT IS THE RESPONSIBILITY OF THE APPLICATOR.* • *Nozzle Type – Solid stream nozzles (such as disc and core with swirl plate removed) oriented straight back produce larger droplets than other nozzle types.* • *Boom Length – Longer booms increase drift potential. Therefore a shorter boom length is recommended.* • *Application Height – Application more than 10 ft. above the canopy increases the potential for spray drift.* ***BOOM HEIGHT*** *Setting the boom at the lowest referenced height (if specified) which provides uniform coverage reduces the exposure of droplets to evaporation and wind. For ground equipment, the boom should remain level with the crop and have minimal bounce.* ***DRIFT REDUCTION TECHNOLOGY (DRT)*** *The EPA Drift Reduction Technology (DRT) Program was developed to encourage the manufacture, marketing, and use of spray technologies scientifically verified to significantly reduce pesticide drift. The use of DRTs should result in significantly less pesticide from spray*	

	applications drifting and being deposited in areas not targeted by those applications, compared to spray technologies that do not meet the minimum DRT standard. EPA-verified drift reduction technologies (DRTs) and their ratings will be added to the following webpage as they become available: https://www.epa.gov/reducing-pesticide-drift/epa-verified-and-rated-drift-reduction-technologies ***WIND*** *Drift potential increases at wind speeds of less than 3 mph (due to inversion potential) or more than 10 mph. However, many factors, including droplet size and equipment type determine drift potential at any given wind speed. AVOID APPLICATIONS DURING GUSTY OR WINDLESS CONDITIONS.* *Note: Local terrain can influence wind patterns. Every applicator needs to be familiar with local wind patterns and how they affect spray drift.* ***TEMPERATURE AND HUMIDITY*** *When making applications in hot and dry conditions, set up equipment to produce larger droplets to reduce effects of evaporation.* ***TEMPERATURE INVERSIONS*** *Drift potential is high during a temperature inversion. Temperature inversions restrict vertical air mixing, which causes suspended droplets to remain close to the ground and move laterally in a concentrated cloud. Temperature inversions are characterized by increasing temperature with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicated good vertical air mixing.* ***SHIELDED SPRAYERS*** *Shielding the boom or individual nozzles can reduce the effects of wind. However, it is the responsibility of the applicator to verify that the shields are preventing drift and not interfering with uniform deposition of the product."*	

Pollinator Advisory Statement for Commercial Agricultural Products	*"POLLINATOR ADVISORY STATEMENT: This product may adversely impact the forage and habitat of local pollinators, including monarch butterfly (and its larvae), birds, or bats if it reaches non-target areas. Protect pollinators by following label directions to minimize spray drift."*	Directions for Use
Runoff Prevention Advisory Statement	*"To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area. Rinsing application equipment over the treated area will help avoid run off to water bodies or drainage systems."*	Directions for Use under the heading "Runoff Prevention"
Label Consistency Statement	*Registrants must also update labels with information listed in Appendix D.*	As specified in the Label Review Manual

Appendix D: Information to Be Provided on All Thidiazuron Product Labels
EPA is requiring that the following information MUST be provided on all thidiazuron labels:

For Each Product:

- formulation type;
- pounds of active ingredient (ai) per gallon of product;
- ensure that the application rates expressed (i.e., lbs ai/acre/year) present the maximum amount of ai for the subject product, or any other product with the subject ai;
- use sites and permitted applicators, include any prohibitions of a user type;
- application equipment;

For Each Target Use Site on the Product:

- maximum single application rate (lbs ai/acre);
- maximum annual application rate (lbs ai/acre/year);
- maximum number of applications per year;
- maximum application rate per crop cycle or season and year (if applicable); (If the target site is not grown in cycles or by seasons, then only express the maximum application rate as an annual maximum rate);
- maximum number of applications per crop cycle or season (if applicable);
- maximum number of times the crop cycle rate can be repeated per year (if applicable);
- application timing – pre-emergent vs. post-emergent;
- application target;
- application type;

If applicable, also include the following information:

- maximum finished spray concentration
- minimum re-treatment interval (expressed in days);
- pre-harvest interval;
- pre-bloom interval;
- pre-grazing interval;
- pre-slaughter interval;
- plant-back interval;
- minimum restricted entry interval (REI);
- minimum personal protective equipment (PPE);

Note the following:

- glove statements – the appropriate gloves must be listed out on the label, per the Label Review Manual (LRM) (Chapter 10). Registrants can no longer reference the category charts;
- precautions should be separate from use restrictions (such as rotational crop restrictions, or restrictions for adjuvants and/or surfactants).